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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

| Applicant's or agent's file reference PC03003-LG | FOR FURTHER ACTION SeeNotificationofTransmittalofInternationalPreliminary Examination Report (Form PCT/IPEA/416) | | | | | | |
|---|---|-----------------------------------|----------------------------|-------------|--|--|--|
| International application No. | International filing date(da | y/month/year ⁱ) | Priority date (day/month/y | ear) | | | |
| PCT/KR2003/000683 | 04 APRIL 2003 (04. | 04.2003) | 08 APRIL 2002 (08.04.20 | 002) | | | |
| International Patent Classification (IPC) or national classification and IPC | | | | | | | |
| IPC7 C07D 471/04 | | | | | | | |
| Applicant LG LIFE SCIENCES LTD. et al | | | | | | | |
| This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. This REPORT consists of a total of sheets, including this cover sheet. This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). | | | | | | | |
| These annexes consist of a total | ofsheets. | | | | | | |
| This report contains indications relating to the following items: I X Basis of the report II Priority III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV Lack of unity of invention V X Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI Certain documents cited VII Certain defects in the international application VIII Certain observations on the international application | | | | | | | |
| Date of submission of the demand | | Date of completion of this report | | | | | |
| 14 OCTOBER 2003 (14.10.2003) | | 22 JUNE 200 | 4 (22.06.2004) | | | | |
| Name and mailing address of the IPEA | | Authorized officer | | A IRALI PA | | | |
| Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea | | KIM, KYOUNC | 3 MI | | | | |
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| T | International aplication No. |
|---|------------------------------|
| | PCT/KR2003/000683 |

| I. | Basis | of the report | | |
|--|-----------|---|--|--|
| 1. | With | regard to the elements of the international application:* | | |
| | X | the international application as originally filed | | |
| | | the description: | | |
| | | pages, as originally filed pages, filed with the demand | | |
| | | pages, filed with the letter of | | |
| | | the claims: | | |
| | | pages, as originally filed pages, as amended (together with any statment) under Article 19 | | |
| | | pages , filed with the demand | | |
| | | pages, filed with the letter of | | |
| | | the drawings: | | |
| | | pages, as originally filed pages, filed with the demand | | |
| | | pages, filed with the letter of | | |
| | | the sequence listing part of the description: | | |
| | | pages, as originally filed pages, filed with the demand | | |
| | | pages, filed with the letter of | | |
| 2. | the i | regard to the language, all the elements marked above were available or furnished to this Authority in the language in which international application was filed, unless otherwise indicated under this item. The elements were available or furnished to this Authority in the following language which is the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). The language of publication of the international application (under Rule 48.3(b)). The language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/ | | |
| 3. | | or 55.3). h regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international iminary examination was carried out on the basis of the sequence listing: | | |
| | brer | contained inthe international application in written form. | | |
| | H | filed together with the international application in computer readable form. | | |
| | \exists | furnished subsequently to this Authority in written form. | | |
| | \exists | furnished subsequently to this Authority in computer readable form | | |
| The statement that the subsequently furnished written sequence listing does not go beyond the disc losure international applicationas as filed has been furnished. | | | | |
| | | The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished. | | |
| 4. | | The amendments have resulted in the cancellation of: | | |
| | | the description, pages | | |
| | | the claims, Nos. | | |
| | | the drawings, sheet | | |
| 5. | | This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).** | | |
| * | | cement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to sopinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 0.17). | | |
| ** | Any r | eplacement sheet containing such amendments must be referred to under item I and annexed to this report. | | |

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| V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | |
|--|-------------------------------|------------------|-------|--------|--|
| 1. 8 | Statement | | | | |
| | Novelty (N) | Claims Claims | 1- 11 | YES | |
|] | Inventive step (IS) | Claims Claims | 1- 11 | YES NO | |
|] | Industrial applicability (IA) | Claims Claims | 1-11 | YES NO | |

2. Citations and explanations (Rule 70.7)

The following documents are referred to in this report; the numbering will be adhered to in the rest of the procedure:

D1: US 5869670 A (Feb. 8, 1999)

D2: WO 0118002 A1 (March 15, 2001) D3: WO 9944991 A1 (Sep. 10, 1999)

1. Novelty

The present invention relates to a method for producing acid salt of gemifloxacin and an intermediate thereof.

The preparation process of Claims 1-10 is novel over D1-D3 since none of the prior art discloses the preparation method for acid salt of gemifloxacin via an intermediate of Formula 4.

Although the compound of Formula 4 has structural similarity to Formula (I) in D1, it differs in an amino-protecting group from Formula (I) in D1. Therefore, the novelty can be acknowledged for the subject matter of Claim 11 [PCT Article 33(2)].

2. Inventive step

D1 and D2 disclose a process of conjugating a naphthyridine carboxylic acid and 3-amiomethyl-4-methoxyiminopyrrolidine (Formula 2 and 3, respectively in the present invention).

In the present invention, the coupling reaction of Formula 2 with Formula 3 and the protection of amino-group are simultaneously preformed, which prevents the production of a by-product. The invention is not considered to be obvious to a person skilled in the art. Furthermore, the present process has advantages of high yield, short reaction time and being purified without recrystallization. Therefore, the subject-matter of Claims 1-10 is considered to involve an inventive step.

(Continued on Supplemental Box)

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Supplemental Box (To be used when the space in any of the preceding boxes is not sufficient) Continuation of: Box V. The subject matter of Claim 11 is also inventive since the compound of Formula 4 is an intermediate compound for the preparation method of Claims 1-10, which is inventive [PCT Article 33(3)]. 3. Industrial applicability The subject-matter of Claims 1-11 appears to be industrially applicable [PCT Article 33(4)].